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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/735,173 | 12/12/2000 | Edward D. Ball | MXI-026DVCN2 | 5414 |

959 7590 10/21/2004

LAHIVE & COCKFIELD, LLP.
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BOSTON, MA 02109

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| EXAMINER |
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YAEN, CHRISTOPHER H

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| ART UNIT | PAPER NUMBER |
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1642

DATE MAILED: 10/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/735,173 | BALL ET AL. | |
| | Examiner | Art Unit | |
| | Christopher H Yaen | 1642 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-27 is/are rejected.
- 7) ☒ Claim(s) 28 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Re: Ball et al
Priority Date: 7 March 1994

1. The amendment filed 7/13/2007 is acknowledged and entered into the record. Accordingly, claims 1-24, and 29-37 are canceled without prejudice or disclaimer.
2. Claims 25-28 are pending and examined on the merits.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. In a telephone interview with applicant's representative on 10/13/2004, examiner offered applicant allowable subject matter drawn to a bispecific molecule comprising a antibody or fragment thereof that binds to the FcγRI coupled to bombesin or gastrin releasing peptide. However, applicant declined to accept allowable subject matter and requested continued prosecution.

Claim Rejections Maintained - 35 USC § 112, 1st paragraph

5. The rejection of claims 25-27 under 35 USC § 112, 1st paragraph is maintained for the reasons of record. Applicant argues that the instant specification meets the requirements under written description guidelines. In particular applicant relies on the fact that the common attributes or features represented in the instant application include features recognized as those defining autocrine growth factors. Applicant further provides specific definitions of autocrine growth factor (see applicant's response page 4) and states that the specification exemplifies several examples of autocrine growth factors, including bombesin, GRP, and functional fragments thereof (see applicant's

response page 4). Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. As stated by the applicant and in the Written Description guidelines, a species that is intended to represent a genus must portray common attributes and features that are representative of the genus claimed. In the instant case, the disclosure of GRP and its analog bombesin fail to meet such requirements. In particular, the genus of autocrine growth factors is diverse and varies in its structure and function. Moreover, the definition of the term in applicant's response (filed 7/13/2004) does not compensate for the lack of disclosure regarding the broad genus of autocrine growth factors claimed. In particular, the characterization of the autocrine growth factors by a broad definition intended to generally define this class of proteins does not suffice as being adequate to define common structures or specific functions in a genus that is highly variant in function and structure. The specification does not offer to one of skill in the art any information with regard to how the species of GRP or bombesin is to relate to other autocrine growth factors in structure and or function. Furthermore, the term "autocrine growth factor" as defined in the response filed 7/13/2004 has not been set forth in the specification as filed, and as such is not sufficient to overcome the rejection of record. The characterization of the growth factors by stating that they are involved in an autogeneuous loop to create a mechanism of growth control is an over simplification of its function. There are many types of factors that act on diverse organs and control diverse cellular systems, all of which have different structures, some of which can act as more than autocrine growth factor (i.e. they also act as paracrine growth factors, such as parathyroid hormone-related protein).

Hence, to describe the genus in this manner does not overcome the lack of disclosure or exemplification of a diverse genus of autocrine growth factors. Moreover, because bombesin is an analog of GRP, this is essentially one species and does not adequately represent the entire genus of autocrine growth factors claimed. Therefore the rejection of claims under 35 USC 112, 1st paragraph is maintained for the reasons of record.

All other rejections are withdrawn in view of the applicant's amendments and arguments thereto as set forth in a paper filed 7/13/2004.

Conclusion

Claims 25-27 are not allowed. Claim 28 is objected to as being dependent on a rejected claim.

Claim 28 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
Art Unit 1642
October 15, 2004



**GARY NICKOL
PRIMARY EXAMINER**